UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

CARLO OLIVA, Derivatively on Behalf of BIOSANTE PHARMACEUTICALS, INC.,	)	Case No.
Plaintiff,	)	
vs.	)	
LOUIS W. SULLIVAN, STEPHEN M. SIMES, FRED HOLUBOW, ROSS J. MANGANO, EDWARD C. ROSENOW, III, STEPHEN A. SHERWIN and JOHN T. POTTS, JR.,	)	
Defendants,	)	
– and –	)	
BIOSANTE PHARMACEUTICALS, INC., a Delaware corporation,	)	
Nominal Defendant.	)	
	)	DEMAND FOR JURY TRIAL

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

By and through his undersigned counsel, plaintiff Carlo Oliva ("Plaintiff") brings this shareholder derivative action on behalf of BioSante Pharmaceuticals, Inc. ("BioSante" or the "Company") and against certain current officers and directors of the Company for breaches of fiduciary duties, abuse of control, gross mismanagement and unjust enrichment. Plaintiff makes these allegations upon personal knowledge as to those allegations concerning Plaintiff and, as to all other matters, upon the investigation of counsel, which included, without limitation: (a) review and analysis of public filings made by BioSante and other related parties and non-parties with the U.S. Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and other publications disseminated by certain of the defendants and other related non-parties; (c) review of news articles, shareholder communications, and postings on BioSante's website concerning the Company's public statements; and (d) review of other publicly available information concerning BioSante and the Individual Defendants (defined herein).

NATURE AND SUMMARY OF THE ACTION

1. This is a shareholder derivative action brought on behalf of BioSante.

2. Between at least February 2010 and December 2011, certain officers and directors of BioSante deliberately misled the Company's shareholders about the commercial viability, efficacy, and market potential for LibiGel, an experimental drug designed to improve the sex drive of women suffering from female sexual dysfunction, and specifically hypoactive sexual desire disorder ("HSDD").

3. More specifically, during the relevant period, the Individual Defendants caused BioSante and its representatives to misrepresent LibiGel's effectiveness over placebo, and provided supposedly reliable "data" concerning LibiGel's "statistically significant" effect on increasing the "number of satisfying events" for women suffering from HSDD. These purportedly positive clinical trials furthered defendants' claims of LibiGel being "the most clinically advanced pharmaceutical

product in the U.S." The Individual Defendants further raised shareholders' expectations by comparing the female market for LibiGel to the male market for erectile dysfunction drugs, quoting an over $2 billion market, and comparing LibiGel to such blockbuster drugs as Viagra, Levitra, and Cialis. In fact, however, LibiGel's actual performance and efficacy fell short of defendants' false statements.

4. The Individual Defendants' house of cards fell down on December 14, 2011, when defendants finally caused BioSante to admit that LibiGel failed to yield positive results in large-scale efficacy tests. According to clinical trial results, women treated with LibiGel did not experience a statistically significant increase in either total satisfying encounters or sexual desire. In fact, in the double-blind placebo-controlled trial, LibiGel did not fare significantly better than the placebo.

5. On this news, the trading price of BioSante's common stock plummeted from $2.12 to $0.48 per share, or 77.3%, in one day. As a result of defendants' unlawful scheme to artificially inflate the trading price of BioSante common stock, the Company has been named as a defendant in a costly and expensive-to-defend class action lawsuit for violations of the federal securities laws. Additionally, the Company's goodwill, reputation and standing in the community have been severely, if not irreparably, injured. Nevertheless, the BioSante Board has still not taken action against defendants to recover damages for the injuries caused by their fiduciary failures. By this action, Plaintiff seeks legal redress for BioSante.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. §1332, as there is complete diversity between Plaintiff and defendants, and the amount in controversy exceeds $75,000.

7. This Court has jurisdiction over each defendant because each defendant is either a corporation that is headquartered in Illinois, or is an individual who has sufficient minimum contacts with Illinois so as to render the exercise of jurisdiction by the Illinois courts permissible under

traditional notions of fair play and substantial justice. This action is not a collusive one to confer jurisdiction on this Court which it would not otherwise have.

8. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because one or more of the defendants either resides in or maintains executive offices in this District, a substantial portion of the transactions and wrongs complained of herein, including the Individual Defendants' primary participation in the wrongful acts detailed herein and aiding and abetting in violation of fiduciary duties owed to BioSante occurred in this District, and defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

PARTIES

9. Plaintiff Carlo Oliva is and has been a shareholder of BioSante since July 11, 2011. Plaintiff is a citizen of the state of New Jersey.

10. Nominal party BioSante is a Delaware corporation with its principal executive offices located at 111 Barclay Boulevard, Lincolnshire, Illinois. According to its public filings, BioSante is a specialty pharmaceutical company focused on developing products for both female sexual health and oncology. BioSante is a citizen of the states of Delaware and Illinois.

11. Defendant Louis W. Sullivan ("Sullivan") has been Chairman of the Board of BioSante since 1998. He also serves on the Audit and Finance, Compensation and Nominating Committees of the BioSante Board. Sullivan received at least $219,000 in fees and other compensation from BioSante. Sullivan is a citizen of the state of Georgia.

12. Defendant Stephen M. Simes ("Simes") has been Vice Chairman of the Board, Chief Executive Officer ("CEO") and President of BioSante since 1998. Simes received at least $1,988,181 in fees and other compensation from BioSante. Simes is a citizen of the state of Illinois.

13. Defendant Fred Holubow ("Holubow") has been a director of BioSante since 1999. He also serves on the Audit and Finance and Nominating Committees of the BioSante Board. Holubow received at least $156,000 in fees and other compensation from BioSante. Holubow is a citizen of the state of Illinois.

14. Defendant Ross J. Mangano ("Mangano") has been a director of BioSante since 1999. He also serves on the Audit and Finance, Compensation and Nominating Committees of the BioSante Board. Mangano received at least $145,000 in fees and other compensation from BioSante. Mangano is a citizen of the state of Illinois.

15. Defendant Edward C. Rosenow, III ("Rosenow") has been a director of BioSante since 1997. He also serves on the Compensation Committee of the BioSante Board. Rosenow received at least $139,000 in fees and other compensation from BioSante. Rosenow is a citizen of the state of Minnesota.

16. Defendant Stephen A. Sherwin ("Sherwin") has been a director of BioSante since 2009. He also serves on the Nominating and Compensation Committees of the BioSante Board. Sherwin received at least $73,000 in fees and other compensation from BioSante. Sherwin is a citizen of the state of California.

17. Defendant John T. Potts, Jr. ("Potts") has been a director of BioSante since 2009. Potts received at least $163,000 in fees and other compensation from BioSante. Potts is a citizen of the state of Massachusetts.

18. The defendants named in ¶¶ 11-17 are referred to collectively in this Complaint as the "Individual Defendants."

THE FIDUCIARY DUTIES OF BIOSANTE'S DIRECTORS AND OFFICERS

19. By reason of their positions as officers, directors, and/or fiduciaries of BioSante and because of their ability to control the business and corporate affairs of BioSante, the Individual

Defendants owed and owe the Company and its shareholders fiduciary obligations of trust, loyalty, and good faith were and are required to use their utmost ability to control and manage BioSante in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of BioSante and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

20. Each director and officer of the Company owes to BioSante and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, performance, management, projections, and forecasts so that the market price of the Company's stock would be based on truthful and accurate information.

CONSPIRACY, AIDING AND ABETTING AND CONCERTED ACTION

21. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

22. During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to mislead shareholders into believing that BioSante was successfully promoting a new and successful product. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.

23. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (a) disguise the Individual

Defendants' violations of law, including breaches of fiduciary duty and unjust enrichment; and (b) disguise and misrepresent the Company's future business prospects.

24. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to make false and misleading statements about the Company's financial condition and business prospects, including regarding the commercial viability, efficacy, and market potential for LibiGel, in BioSante's shareholder reports and public filings. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

25. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commissions of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

FACTS COMMON TO ALL CAUSES OF ACTION

26. BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. Over the past decade, BioSante has been in the process of developing LibiGel, a drug designed to improve the sex drive of women suffering from sexual dysfunction, and specifically HSDD.

27. HSDD is a persistent lack or absence of sexual desire, fantasies, or thoughts. It is the most common form of female sexual dysfunction. Approximately 43% of women ages 18-59 experience some form of sexual dysfunction. As a result, the anticipated U.S. Food and Drug Administration ("FDA") approval of LibiGel was viewed as an important breakthrough.

28. LibiGel is a gel formulation of testosterone designed to be quickly absorbed through the skin after application on the upper arm, delivering testosterone to the bloodstream evenly over time and in a non-invasive and painless manner. Since at least February 2010, BioSante had two Phase III clinical trials in progress covered by a Special Protocol Assessment ("SPA") with the FDA to demonstrate the safety and efficacy of LibiGel in the treatment of HSDD.

29. On February 22, 2010, the Individual Defendants caused BioSante to issue a press release announcing positive safety data for LibiGel in its Phase III clinical development program. This press release stated in part:

> BioSante Pharmaceuticals, Inc., today announced additional positive safety data in its ongoing LibiGel Phase III clinical development program. For the second time, unblinded data have been reviewed by the independent DMC of the LibiGel Cardiovascular and Breast Cancer Safety Study. Based on this review, the DMC once again unanimously recommended continuation of the study as described in the FDA-agreed LibiGel safety study protocol, with no modifications.
>
> BioSante reported that the DMC reviewed all unblinded adverse events in the safety study including all serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. To date, there have been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. Therefore, in view of the DMC recommendation, the BioSante LibiGel Phase III development program will continue as planned. BioSante targets mid-2011 for submission to the FDA of a new drug application (NDA).
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> * * *
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> The DMC, which for the second time, reviewed the LibiGel safety data on an unblinded basis, confirms what we have learned from the blinded data, that LibiGel does not pose a safety risk to the women in the study, said Stephen M. Simes, BioSante's president and CEO. A DMC can recommend continuing, changing or stopping a study and their main responsibility is to ensure that subjects recruited to the study are not exposed to unnecessary safety risks. Therefore, the DMC's recommendation to continue the LibiGel safety study unchanged is the best possible outcome of the DMC's second unblinded review of all adverse events. This is very good news for BioSante and for women since LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in surgically menopausal women. ***We continue to believe that LibiGel can be the first product approved by the FDA for this common and unmet medical need, also referred to as female sexual dysfunction (FSD).***

* * *

In addition to the Phase III Cardiovascular and Breast Cancer Safety Study, BioSante is conducting two LibiGel Phase III efficacy trials. The Phase III efficacy trials of LibiGel in the treatment of FSD are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The efficacy trials are being conducted under an FDA approved SPA (special protocol assessment agreement).

As previously announced by BioSante, treatment with LibiGel in a Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline (p<0.0001); this increase also was significant versus placebo (p<0.05). In this study, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, conducted in the United States, in surgically menopausal women distressed by their low sexual desire and activity.

30. On May 14, 2010, the Individual Defendants caused BioSante to issue a press release announcing its financial results for the first quarter of 2010, ended March 31, 2010, and discussing recent developments. This release stated in part:

- **Positive LibiGel® Safety Data in Ongoing Phase III Clinical Development Program**: For the second time, unblinded safety data were reviewed by the independent Data Monitoring Committee (DMC) of the LibiGel Cardiovascular and Breast Safety Study. The LibiGel safety study continues, with no modifications, based on the excellent safety profile observed to date.

* * *

BioSante incurred a net loss of approximately $10.5 million or $(0.19) per share for the quarter ended March 31, 2010, compared to a net loss of $4.1 million or $(0.15) per share for the same period in 2009. This expected increase in net loss was due primarily to the conduct of the three ongoing LibiGel® (testosterone gel) Phase III clinical studies to support submission of a new drug application (NDA) and U.S. Food and Drug Administration (FDA) approval. The LibiGel Phase III safety and efficacy studies are being conducted under an FDA approved SPA (special protocol assessment).

31. On June 21, 2010, the Individual Defendants caused BioSante to issue a press release entitled "BioSante Pharmaceuticals Says FDA Advisory Committee Recommendation Against Flibanserin Has No Impact on LibiGel®." This release stated in part:

> "There are important scientific differences between the way LibiGel and flibanserin work on the body, and differences in their clinical development programs," stated BioSante President and CEO Stephen M. Simes. "The LibiGel safety and efficacy trials are being conducted under an SPA (Special Protocol Assessment) agreement with the FDA, a level of agreement that the flibanserin program did not have. BioSante also is conducting a large safety study comparing LibiGel to placebo to show cardiovascular and breast-cancer safety. We are pleased also by comments made by the Advisory Committee stressing the need for a product to treat this unmet medical need. ***Given the recommendation of the Advisory Committee, we believe that LibiGel is positioned to be the first product approved for the treatment of HSDD.***"
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> "The Advisory Committee's judgment on flibanserin has no impact on the clinical development program of LibiGel and is not relevant to the potential for FDA approval of LibiGel for the treatment of HSDD in menopausal women," said Michael C. Snabes, MD, PhD, BioSante's vice president of clinical development.

32. On October 18, 2010, the Individual Defendants caused BioSante to issue a press release entitled "BioSante Pharmaceuticals Reaches Key LibiGel Safety Study Enrollment Target." This release stated in part:

> "This milestone gives BioSante our first opportunity potentially to declare completion of enrollment in the safety study," stated Michael C. Snabes, M.D., Ph.D., BioSante's senior vice president of medical affairs. "We have had an extremely low number of cardiovascular and breast cancer events to date, as well as three previous favorable DMC recommendations. We expect the study to demonstrate the safety of LibiGel in the treated population, regardless of whether the DMC stops enrollment at 2,500 women or we need to continue enrollment."

33. Two weeks later, on October 26, 2010, the Individual Defendants caused BioSante to issue a press release entitled "BioSante Pharmaceuticals Reports Positive LibiGel® Data Monitoring Committee Recommendation – No safety issues observed, study to continue as per protocol without modifications." This release stated in part:

> "We are very pleased that the DMC recommended that the study should continue without modification. This means that there are no general or specific safety issues based on their unblinded review of adverse events. The low number of CV

events to date is consistent with the safety of testosterone in women". . . . "Once the DMC determines that there are enough subjects enrolled for statistical significance, enrollment of new subjects into the study will be complete. The current LibiGel safety study protocol allows for up to 4,000 women to be enrolled."

* * *

"***With this most recent favorable DMC recommendation, we continued to believe that LibiGel will be the first product approved by the FDA to treat HSDD in menopausal women, also referred to as FSD***," said Stephen M. Simes, BioSante's president and CEO.

34. On November 12, 2010, the Individual Defendants caused BioSante to file its Form 10-Q with the SEC publicizing the development of its purportedly breakthrough new drug for the treatment of HSDD. This SEC Form 10-Q stated in part:

> We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need, for which presently there is no FDA approved pharmaceutical product. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women.

35. On December 27, 2010, the Individual Defendants caused BioSante to issue a press release entitled "BioSante Pharmaceuticals to Raise $18 Million in Registered Direct Offering." This release stated in part:

> BioSante Pharmaceuticals, Inc. today announced that it has received commitments from several institutional investors to purchase $18 million of securities in a registered direct offering. . . .
>
> "We are pleased to have a commitment from these new and existing institutional investors," said Stephen M. Simes, BioSante's president and chief executive officer. "This additional funding from these high quality biotechnology institutional investors provides us with a strong cash position as we close out the year, ensuring our ongoing focus on our LibiGel® Phase III clinical study program. Our objective is to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2011. LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual

> desire disorder (HSDD) in menopausal women, and ***we continue to believe that LibiGel has the potential to be the first product approved by the FDA for this common and unmet medical need***."

36. On this positive news, BioSante's share price skyrocketed, increasing over 26%, to close at $2.00 per share on December 27, 2010.

37. On December 31, 2010, BioSante completed an offering for 10.6 million shares of the Company's common stock and warrants to purchase 5.3 million additional shares. This offering resulted in $16.9 million in net proceeds for the Company.

38. On March 4, 2011, the Individual Defendants caused BioSante to issue a press release announcing another registered direct offering and reiterating and repeating its expectation to be the first company to have a drug approved by the FDA to treat HSDD. This release stated in part:

> "We are pleased to have this commitment from these new and existing institutional investors," said Stephen M. Simes, BioSante's president and chief executive officer. "This additional funding provides us with added financial power to continue to fund our ongoing LibiGel® Phase III clinical study program. We recently announced completion of enrollment in the first of the two LibiGel Phase III efficacy trials and expect to announce completion of enrollment in the second in the near future. LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and ***we continue to believe that LibiGel has the potential to be the first product approved by the FDA for this common and unmet medical need***."

39. On March 9, 2011, the Individual Defendants caused BioSante to announce the completion of the direct offering of 12.2 million shares of the Company's common stock and warrants to purchase 4.0 million additional shares. This offering resulted in $23.8 million in net proceeds for the Company.

40. On March 16, 2011, the Individual Defendants caused BioSante to issue a press release announcing its financial results for 2010 and reporting on the Company's clinical development. This release stated in part:

> "We are very pleased with our progress over the last year as well as our current cash balance," said Stephen M. Simes, BioSante's president and CEO. "Through careful cash management and our financing strategy, we believe we now have removed any

near-term financial risk from BioSante, and our current cash balance is sufficient to finance our operations and LibiGel clinical development well into 2012, without needs for additional funds."

* * *

LibiGel® Clinical Highlights

The increased LibiGel clinical development expenses during 2010 was the result of steady progress in BioSante's LibiGel Phase III clinical program. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women, for which there is no FDA-approved product. In February 2011 the company announced completion of enrollment in the first of two LibiGel Phase III efficacy trials, and expects enrollment in the second efficacy trial to be completed in the near future. BioSante continues to expect data from the two efficacy trials in Fall 2011.

41. On the same date, the Individual Defendants caused BioSante to file its Form 10-K with the SEC announcing the requirements remaining for its submission of a new drug application for, and approval by the FDA of, LibiGel. This SEC Form 10-K stated in part:

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future. The Phase III safety is currently enrolling women, and as of the end of February 2011 had enrolled approximately 2,900 women. In February 2011, we announced that based upon the fifth review of study conduct and unblended safety data from the safety study by the study's independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If enrollment is not completed sooner, enrollment will continue until completion of the statistical analyses of the safety study and efficacy trials, ***we intend to submit an NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women. It is our objective to submit the LibiGel NDA to the FDA so that LibiGel may be approved in 2012.***

* * *

> We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of HSDD in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. We have three SPAs in place concerning LibiGel. The first SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for "surgically" menopausal women. The second SPA covers our LibiGel program in the treatment of FSD in "naturally" menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

42. On March 30, 2011, the Individual Defendants caused BioSante to issue a press release entitled "BioSante Pharmaceuticals Completes Enrollment in Both Pivotal LibiGel® Phase III Efficacy Trials." This release stated in part:

> BioSante Pharmaceuticals, Inc. today announced that enrollment of subjects in the second of two pivotal Phase III LibiGel (testosterone gel) safety and efficacy trials has been completed. Enrollment in the first LibiGel efficacy trial was completed in February. The efficacy trials are being conducted under an FDA-approved special protocol assessment (SPA) agreement. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women, for which there is no FDA-approved product.
>
> "This is an important achievement for BioSante and a key step toward completing the LibiGel Phase III clinical development program . . . . There are more than 1,000 subjects in the efficacy trials and we anticipate announcing top-line efficacy data this fall."

43. On May 31, 2011, the Individual Defendants caused BioSante to issue a press release supporting its prospects of creating the first product approved by the FDA for the treatment of HSDD by hyping a "90 percent predictive probability of success." This release stated in part:

> "LibiGel remains the only product in the world in Phase III clinical development for the treatment of HSDD," said Stephen M. Simes, BioSante's president & CEO. "The ability to stop enrollment as per the sample size analysis that indicates ***a 90 percent predictive probability of success is very encouraging for the outcome of our LibiGel Phase III clinical development program. With this most***

> ***recent development, we continue to believe that LibiGel will be the first product approved by the FDA to treat HSDD***, also referred to as FSD, in menopausal women."

44. As a result of this news, BioSante's stock continued to trade at artificially inflated levels, reaching a high of $3.81 on July 12, 2011, an increase of nearly 150% compared to the price of the stock before defendants embarked on the unlawful marketing scheme.

45. On August 5, 2011, the Individual Defendants caused BioSante to file its Form 10-Q with the SEC, which misrepresented, among other things, that "LibiGel remains the most clinically advanced pharmaceutical product in the U.S." This Form 10-Q stated in part:

> We believe ***LibiGel remains the most clinically advanced pharmaceutical product in the U.S.*** in active development for the treatment of hypoactive sexual desire disorder in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need.

THE TRUTH IS REVEALED

46. On December 14, 2011, the Individual Defendants caused BioSante to issue a press release revealing for the first time to investors that LibiGel had failed to yield positive results in large-scale efficacy tests designed by the Company. According to the clinical trial results, women treated with LibiGel did not experience a statistically significant increase in either total satisfying sexual encounters or sexual desire. In fact, in the double-blind placebo-controlled trial, LibiGel did not fare significantly better than the placebo. More specifically, defendants admitted:

> "We obviously are very disappointed by the Phase III LibiGel efficacy trial results. We have been committed to LibiGel for many years and we are committed to determining the future of LibiGel," stated Stephen M. Simes, BioSante's president & CEO. "We will continue to analyze the efficacy trial data fully and determine plans for our next steps in the LibiGel development plan, and provide an update at a later time. While the LibiGel Phase III cardiovascular and breast cancer safety study currently continues as planned, we will be analyzing the best path forward for the study given the results reported today. I want to thank our entire BioSante clinical team and the clinical investigators for their tireless efforts in these trials, and I also want to thank the women enrolled in the BLOOM trials for their participation."

47. On this news, BioSante's share price collapsed $1.64 per share, or 77%, instantly wiping out tens of millions of dollars in shareholders' equity.

48. The negative clinical trial results came as a big surprise to BioSante shareholders and analysts alike, as there was a consensus emerging in the market that LibiGel had a 70%-80% probability of FDA approval. Defendants caused shareholders and analysts to believe that most of the negatives with LibiGel were safety-related and that the drug's efficacy was almost a foregone conclusion. In fact, of the eight analysts who covered BioSante stock, five rated it a strong buy and three a buy-no holds, no underperforms, and no sells. And the median price target was $5.88, with high targets ranging between $7 and $8.

DAMAGES TO BIOSANTE

49. As a result of defendants' false statements, BioSante has been severely injured and damaged. Millions of dollars in shareholders' equity has been wiped out. Worse yet, the Company has been exposed to the risk of massive liability for violating the federal securities laws. Indeed, BioSante already has been named as a defendant in a costly and expensive-to-defend securities class action lawsuit.

50. Moreover, these actions have irreparably damaged BioSante's corporate image and goodwill. For at least the foreseeable future, BioSante will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that BioSante's ability to raise equity capital or debt on favorable terms in the future is already impaired.

DERIVATIVE ALLEGATIONS

51. Plaintiff brings this action derivatively in the right and for the benefit of BioSante to redress injuries suffered, and to be suffered, by BioSante as a direct result of the Individual Defendants' breaches of fiduciary duty and unjust enrichment, as well as the aiding and abetting

thereof, by the Individual Defendants. BioSante is named as a nominal defendant solely in a derivative capacity.

52. Plaintiff owns BioSante stock and continuously held the Company's stock during the times relevant to defendants' alleged misconduct. Insofar as Plaintiff alleges facts that occurred prior to his ownership of BioSante stock, those facts are to show a pattern and practice of misconduct in support of Plaintiff's claims, which claims seek relief for breaches of loyalty that arose during Plaintiff's ownership of BioSante stock. Plaintiff will adequately and fairly represent the interests of BioSante in enforcing and prosecuting its rights.

DEMAND FUTILITY ALLEGATIONS

53. Plaintiff did not make a pre-suit demand on the Board to pursue this action, because such a demand would have been a futile and wasteful act for the following reasons.

54. First, the members of BioSante's Board have demonstrated their unwillingness and/or inability to act in compliance with their fiduciary obligations and/or to sue themselves and/or their fellow directors and allies in the top ranks of the corporation for the violations of law complained of herein. These are people they have developed professional relationships with, who are their friends and with whom they have entangling financial alliances, interests and dependencies. Therefore, the Board is not able to and will not vigorously prosecute any such action.

55. Second, the BioSante Board participated in, approved and/or permitted the wrongs alleged herein to have occurred, participated in efforts to conceal or disguise those wrongs from BioSante's shareholders, or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties. As a result of their access to and review of internal corporate documents, or conversations and connections with other corporate officers, employees, and directors and attendance at management and/or Board meetings, each of the defendants knew or recklessly disregarded the adverse non-public information regarding BioSante's

business and financial condition, and specifically that LibiGel failed to yield positive results compared to placebo and in efficacy tests and, therefore, was unlikely to receive FDA approval and/or have significant market potential. Pursuant to their specific duties as Board members, the members of the BioSante Board are charged with managing the Company and conducting its business affairs. Defendants breached the fiduciary duties of loyalty, candor and good faith owed to BioSante by making false and misleading statements about the Company's financial condition and business prospects, including regarding the commercial viability, efficacy, and market potential for LibiGel, in BioSante's shareholder reports and public filings. The BioSante Board cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action, because each of its members participated in the wrongdoing or are dependent upon other defendants who did.

56. Third, the acts complained of constitute violations of the fiduciary duty of loyalty (and candor and good faith) owed by BioSante directors and these acts are incapable of ratification.

57. Fourth, the members of BioSante's Board have benefited, and will continue to benefit, from the wrongdoing herein alleged; have engaged in such conduct to preserve their positions of control and the prerequisites derived thereof; and are incapable of exercising independent objective judgment in deciding whether to bring this action.

58. Fifth, any suit by the directors of BioSante to remedy these wrongs would likely further expose defendants to liability under the federal securities laws, which could result in additional civil and/or criminal actions being filed against one or more of the defendants. Thus, they are hopelessly conflicted in making any supposedly independent determination whether to sue themselves.

59. Sixth, BioSante has been and continues to be exposed to significant losses due to the wrongdoing complained of herein, yet the BioSante Board has not filed any lawsuits against

defendants or others who were responsible for that wrongful conduct to attempt to recover for BioSante any part of the damages BioSante suffered and will suffer thereby.

60. Seventh, demand is excused because the conduct alleged herein, including the issuance of false and misleading statements to shareholders, was not the product of a valid exercise of business judgment. The conduct of the directors/defendants alleged herein, including the issuance of false and misleading statements to shareholders, was so egregious on its face that Board approval cannot meet the test of business judgment, and a substantial likelihood of director liability for breach of fiduciary duty therefore exists.

61. Eighth, defendant Simes is employed full-time by the Company, and has received and continues to receive substantial monetary compensation as a result of that employment. Defendant Simes will act to preserve and not threaten his position of control and the prerequisites thereof, and is therefore incapable of exercising independent objective judgment in deciding whether to bring this action.

62. Plaintiff has not made any demand on shareholders of BioSante to institute this action since such demand would be a futile and useless act for the following reasons:

(a) BioSante is a publicly traded company with approximately 109 million shares outstanding, and thousands of shareholders;

(b) Making demand on such a number of shareholders would be impossible for Plaintiff who has no way of finding out the names, addresses or phone numbers of shareholders; and

(c) Making demand on all shareholders would force Plaintiff to incur huge expenses, assuming all shareholders could be individually identified.

COUNT I

(Breach of Fiduciary Duty Against Defendants)

63. Plaintiff incorporates the allegations above as though fully set forth below.

64. Defendants owe BioSante fiduciary duties of loyalty, candor and good faith.

65. Defendants have violated their fiduciary duties of loyalty, candor and good faith. More specifically, defendants, in breach of these fiduciary duties, made and/or participated in making false statements and omitted to disclose adverse material non-public information regarding the Company's financial condition and business prospects, specifically the commercial viability, efficacy, and market potential for LibiGel, in BioSante's shareholder reports.

66. By reason of the foregoing acts, practices and course of conduct, defendants have failed to faithfully discharge their fiduciary duties owed to BioSante and its shareholders.

67. As a proximate result of defendants' misconduct, BioSante has been injured and is entitled to damages.

COUNT II

(Abuse of Control Against Defendants)

68. Plaintiff incorporates the allegations above as though fully set forth below.

69. At all relevant times, defendants employed an unlawful scheme for the purpose of maintaining and entrenching themselves in their positions of control, power, prestige and profit at BioSante. As a part of this scheme, defendants made and/or participated in the making of misrepresentations regarding BioSante's financial condition and business prospects.

70. Defendants' conduct constituted an abuse of their ability to control and influence BioSante.

71. As a proximate result of defendants' misconduct, BioSante has been injured and is entitled to damages.

COUNT III

(Gross Mismanagement Against Defendants)

72. Plaintiff incorporates the allegations above as though fully set forth below.

73. Defendants owed BioSante a fiduciary duty to competently and lawfully direct its business and affairs. In derogation of that fiduciary duty, defendants grossly mismanaged BioSante by causing it to issue false and misleading statements about the Company's financial condition and its business prospects to BioSante shareholders and the public alike. As a result, BioSante now faces potentially massive liability for violations of the federal securities laws. Indeed, the Company already has been named as a defendant in a costly and expensive-to-defend class action lawsuit.

74. As a proximate result of defendants' misconduct, BioSante has been injured and is entitled to damages.

COUNT IV

(Unjust Enrichment Against Defendants)

75. Plaintiff incorporates the allegations above as though fully set forth below.

76. As a result of the misconduct particularized herein, defendants have been unjustly enriched at the expense of BioSante, in the form of unjustified fees, salaries, stock awards and other emoluments of office.

77. All the payments and benefits provided to defendants were at the expense of BioSante. The Company received no benefit from these payments.

78. As a proximate result of defendants' misconduct, BioSante has been injured and is entitled to damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Awarding money damages against all defendants, jointly and severally, for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest, to ensure that defendants do not participate therein or benefit thereby;

B. Directing all defendants to account for all damages caused by them and all profits, special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all fees, salaries, stock awards and other payments, and imposing a constructive trust thereon;

C. Directing BioSante to take all necessary actions to reform and improve its corporate governance and internal control procedures to comply with applicable law, including, but not limited to, the federal securities laws and state corporation laws regarding fiduciary duties of loyalty, candor and good faith;

D. Awarding punitive damages;

E. Awarding costs and disbursements of this action, including reasonable attorneys', accountants' and experts' fees; and

F. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: May 22, 2012

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